### U.S. PATENT APPLICATION

#### FOR

# 5 PROCESS FOR PRODUCING A CHANNEL CLEANING BRUSH FOR CLEANING AN ENDOSCOPE OPERATING CHANNEL

#### BY

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#### FIELD OF THE INVENTION

This invention relates to endoscopes. More particularly, this invention relates to the operating channels of these endoscopes.

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#### **BACKGROUND**

Endoscope operating channels make it possible to move biopsy pincers to an operating site in order to take tissue samples at that location.

Repeated passage of the biopsy pincers into the operating channels, and in particular the passage of rigid elements of these devices into curves formed by the channels once introduced into the

human body, has damaging effects on the operating channels. These effects include scraping of the internal walls, creation of diverticula therein, creation of perforations therein, and even promotion of the creation of biofilms by coating the walls thereof, thus increasing the risks of contamination of the pincers before they arrive at the operating site.

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In order to prevent these effects or risks, i.e. in order, after each usage, to remove the biofilm which may have been deposited, it is normal practice to use channel cleaning brushes, which are small brushes with handles similar to those used domestically for cleaning bottles or other containers.

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For such usage the brushes are formed by attaching a group of synthetic material bristles to flexible "handles" or flexible cores that are sufficiently long to permit the brushes to pass from one end of the channel to the other.

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Channel cleaning brushes are produced and packaged singly. In addition, their manufacture involves several production phases including at least preparation of the cores and the brushes, mounting of the brushes onto the cores, and packaging of the channel cleaning brush. These constraints make cleaning of the operating channels expensive, especially since the channel cleaning brushes are thrown away after every use.

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US 5 964 004 discloses cleaners for tubes such as endoscope operating channels, and proposes blades on a sheath mounted on a flexible core, the blades and the sheath being integrally moulded on the flexible core and being made of rubber or synthetic material, the core being a

steel wire.

WO01 28406 proposes materials that can be used and means of attaching a brush to a core, which is a filament of extruded propylene onto which the brush is over-moulded.

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The applicant has sought to provide a greater reduction in the manufacturing costs for channel cleaning brushes.

#### SUMMARY OF THE INVENTION

The invention relates to a process for producing a channel cleaning brush for cleaning an endoscope operating channel, including mounting on a flexible core at least one synthetic material brush having a cleaning coil disposed on a shaft. Preferably, the synthetic material brush is over-moulded onto the core. The process is characterised by the fact that a plurality of brushes may be over-moulded onto the core.

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Preferably, the core is pre-cut between two brushes, allowing the core to be cut and separated into two strands.

Preferably, a pre-cutting point connector including a breaking point between the two strands is over-moulded onto the core.

#### BRIEF DESCRIPTION OF THE FIGURES

The invention will be better understood with the aid of the following description and of the

accompanying drawings, in which:

- Figure 1 is a simplified view of a channel cleaning brush in accordance with the invention;
- Figure 2 shows a transverse cross-sectional view of a channel cleaning brush in front of the last fin:
- 5 Figure 3 shows a perspective view of elements of the mould;
  - Figure 4 shows a partial axial cross-sectional view of a brush;
  - Figure 5 shows the principle of manufacture and packaging of a group of channel cleaning brushes;
  - Figure 6 shows an example of a pre-cutting segment; and
- Figure 7 shows a perspective view of an example of a half-mould.

#### DETAILED DESCRIPTION OF THE INVENTION

With reference to **Figure 1**, channel cleaning brush **1** has a core **10** of synthetic material thread such as Teflon or polytetrafluoroethylene (PTFO), which is flexible and of good mechanical quality, on which a brush **15** is attached, itself being formed by a shaft **20** bearing brushing or scraping fins **21**. The brush **15** is in this case made as a single piece of moulded synthetic material, for example, low density polyethylene, the flexibility of which permits the walls of the operating channel to be brushed without damaging or deforming them.

The fins shown in **Figure 2** are of a shape covering substantially one sector, in the case of fins with only one blade, or n sectors, in the case of fins with n blades, of the transverse cross-section of the operating channel of which they are intended to scrape the walls.

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Figure 2 shows the relative placement of the fins 21, in this case in two sectors of substantially an angle  $\alpha$  with respect to the centre, which are inscribed in a circle with a diameter D corresponding to the diameter of the section of the channel to be scraped, or a little greater; its shaft 20 to which it is attached, with a diameter d; and the core 10 of the channel cleaning brush.

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As shown in Figure 4, which is a partial axial cross-section of a brush, the fins 21 are regularly disposed axially on the shaft 20, spaced apart from each other by a distance e which is not particularly large, for example equal to D-d.

Similarly the fins 21 are regularly disposed in an angled manner, i.e. two successive fins 21 are axially rotated by an angle  $\alpha$  in relation to each other. For this reason it is possible to refer to a cleaning coil although the fins themselves are not twisted.

In the example of Figure 2, the angle  $\alpha$  is equal to  $\pi/2$ , and the fin 21 following the fin shown would cover the angle  $\beta$  of the figure.

Thus in this example two successive fins with two blades would be sufficient to scrape the whole wall of the channel.

More generally, a brush will be formed by at least  $2\pi/(n\alpha)$  fins with n blades to cover the whole periphery of the wall.

In this case there is a preference for n = 2 blades and an angle  $\alpha$  equal to  $\pi/2$ , which achieves an

advantage during manufacture since a single cutting plane 40 is provided, illustrated in Figures 2 and 4, for all the fins in their final position on the shaft of the brush.

Thus it is possible to mould the fins 21 and the shaft 20 simultaneously in order to produce a single unified piece. Moreover, a mould 30', 30'', shown in Figure 5, is provided to over-mould the brushes 15 directly onto the flexible core 10 of the channel cleaning brush.

The over-moulding operation is of the fusion diecasting type in this case.

The core 10 is held taut between a supply spool 50 dispensing PTFO thread (to serve as the core) and a receiving spool 60 receiving the formed channel cleaning brushes, which are ready for dispatch. Between the two spools the mould 30', 30" over-moulds the brushes 15 onto the thread 10 by means of depressions 32a, 32b, shown in Figure 3, at locations predetermined by the advancement of the thread between the two spools and the position of the depressions in the mould. The brushes are fixed to the core in a purely thermal manner, with the temperature reached during the over-moulding operation, which is effected by fusion, causing superficial melting of the PTFO thread. Pre-cutting points for the core 10 at the ends 2, 3 of the channel cleaning brushes are formed simultaneously with the brushes at predetermined sites 70 relative to the depressions 32a, 32b in the mould, these pre-cutting points being located between two brushes 15 so that the brushes can be separated when about to be used.

Figure 6 shows a particular embodiment of these pre-cutting points in which the PTFO thread of the core 10 is cut at 11, the two strands 10', 10" are separated in order to leave a gap 12

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between them, and a connector 23, itself including a breaking point 24 between the two strands, is over-moulded onto the two strands 10', 10" while preserving this gap.

Users are thereby provided with spools of channel cleaning brushes which are very easy to use.

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The manufacturing tool for such a connector in the tool for manufacturing the brushes described hereinunder can easily be produced.

It is also necessary to provide a knife for cutting the core, pincers for grasping the two ends thus obtained and means for separating these ends by the gap 12 and positioning them on both sides of the pre-cutting point 70 of the mould. It is also necessary to control these means before the moulding operation itself.

The mould itself must comprise the depressions for these segments at the sites 70.

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It would also be possible to dispense with pre-cutting segments, allowing the user to cut the channel cleaning bushes himself but this would remove one of the advantages of the invention.

In Figure 3 the mould 30', 30" has two complementary blocks 30', 30" corresponding to two half moulds. When in contact the two blocks are separated at their contact face by a cutting plane 40, partially illustrated in Figure 4 and indicated in Figure 2. A block 30' or 30" is formed by a stack of elements 31a, 31b, each element having two halves 32a, 32b that are half the thickness of a fin depression, with the stacked arrangement producing the full thicknesses,

and the two blocks forming the complete depressions. The two depression halves 32a, 32b are connected by a half-depression 38 for a segment of the shaft of the brush. This design requires termination elements having only half the depression thickness. It is possible to design elements (not shown) having only the complete thickness of a half-depression. The termination blocks are thus no longer necessary.

It is also possible to design (Figure 7) half-moulds 100 that are non-modular.

For other types of fins the design of the mould would be more complex.

The process for producing the channel cleaning brushes is consequently the following:

assuming that the flexible core 10 is in place in the open mould 30', 30",

- 1) the brush or brushes 15 are over-moulded onto this flexible core after having closed the two blocks 30', 30" one on the other, the brushes being over-moulded and at the same time thermally fixed at locations predetermined by the position of the core in the mould,
  - 2) a pre-cutting point connector 23, 24 for the core 10 is simultaneously moulded at a predetermined location 70 on the channel cleaning brush,
  - 3) the mould 30', 30" is opened and the brush or brushes 15 are demoulded,
  - 4) the supply spool 50 is turned to unwind the core 10 with no brushes applied by a length of

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flexible core corresponding to a moulding operation, this length being positioned in the block 30',

- 5) and the receiving spool 60 is turned simultaneously by the length of the core corresponding to
- 5 the moulding operation which has just been effected to wind the core bearing the brushes by a corresponding length.